



April 3, 2020

Donald Rucker, MD
National Coordinator for Health Information Technology
US Department of Health and Human Services
Washington, DC 20201

Dear Dr. Rucker:

On behalf of the Healthcare Information and Management Systems Society ([HIMSS](#)) and the Personal Connected Health Alliance ([PCHAlliance](#)), we are pleased to provide written comments in response to the [Draft 2020-2025 Federal Health IT Strategic Plan](#), which was published January 15, 2020. HIMSS and PCHAlliance appreciate the opportunity to leverage our members' expertise in offering feedback on this Strategic Plan and helping to promote a health information technology (health IT) landscape that can increase transparency, competition, and consumer choice, while also seeking to protect the privacy and security of individuals' health information.

HIMSS is a global advisor and thought leader supporting the transformation of the health ecosystem through information and technology. As a mission-driven non-profit, HIMSS offers a unique depth and breadth of expertise in health innovation, public policy, workforce development, research and analytics to advise global leaders, stakeholders and influencers on best practices in health information and technology. Through our innovation engine, HIMSS delivers key insights, education and engaging events to healthcare providers, governments and market suppliers, ensuring they have the right information at the point of decision. Headquartered in Chicago, Illinois, HIMSS serves the global health information and technology communities with focused operations across North America, Europe, the United Kingdom, the Middle East and Asia Pacific. Our members include more than 80,000 individuals, 480 provider organizations, 470 non-profit partners, and 650 health services organizations.

PCHAlliance, a membership-based HIMSS Innovation Company, accelerates technical, business and social strategies necessary to advance personal connected health and is committed to improving health behaviors and chronic disease management via connected health technologies. PCHAlliance is working to advance patient/consumer-centered health, wellness and disease prevention. The Alliance mobilizes a coalition of stakeholders to realize the full potential of personal connected health. PCHAlliance members are a vibrant ecosystem of technology and life sciences industry icons and innovative, early stage companies along with governments, academic institutions, and associations from around the world.

HIMSS and PCHAlliance support the Strategic Plan's outcomes-driven approach and goals focused on meeting the needs of individuals, populations, caregivers, healthcare providers, payers, researchers, developers, and innovators. We agree that the entire community has worked together to help digitize health information and healthcare, but work remains to ensure patients and caregivers have access to information they value and can use. Building an integrated ecosystem that collects data from multiple sources is critical for these tools to unlock the power of data.

We suggest there is considerable value in the Strategic Plan placing greater emphasis on advancing health information infrastructure that enables individuals to take more control over their personal health and wellness through access to their personal health data and digital tools that educate and guide personal health decisions that support health and wellness. When patients, caregivers, and healthcare providers are equipped with complete and accurate health data, they can work together to establish comprehensive and tailored care plans, make informed decisions about care to achieve health goals, and leverage analytic tools to identify risk to encourage preventive care aimed at keeping people well. Ultimately, advancing health information infrastructure to enable people to self-manage their health and wellness leads to improved outcomes and more meaningful engagement between patients and providers. A key dimension of digital health systems is an interoperable health IT infrastructure able to move data to stakeholders, where the patient is a full partner with clinicians in establishing personal health goals and tracking progress of care towards goals, all made possible by health IT to empower individuals.

HIMSS and PCHAlliance are aligned with how the Strategic Plan highlights the importance of the shift to value-based care through new incentives for healthcare providers to improve quality and patient outcomes. Real focus is placed on how healthcare provider success in value-based payment models is contingent upon access to robust data and analytic tools, at the point of care, that allows the provider to accurately understand patient needs and track improvement towards health goals over time. We also appreciate the drive to minimize clinician burden through strategies that incorporate technologies into existing workflows that automate reporting to further reduce workload burden.

It is important to note how the COVID-19 global pandemic is having a devastating impact on populations, and will require intensive recovery efforts to restore health system capacity to deliver care that is meaningful and connected to individuals and communities, and tracks outcomes to ensure every individual receives care that achieves the best possible outcomes. Health systems continue to struggle to manage growing demands for care, and ensure they have the products, equipment, and supplies to support clinicians to deliver quality care. Overall, the key to advancing and strengthening population health and wellness is transformation of today's healthcare system toward the future, digitally-enabled health system, that is able to mobilize as well as transform data into knowledge

and insights that inform care delivery focused on keeping people and populations healthy and well.

While digital health is widely viewed as the future of sustainable and high-performing healthcare, until now, digital health has been defined from the perspective of technology, rather than what health information technologies can achieve for global populations. To advance and inform the progress of digital health across global health systems, clearly defining digital health offers health systems greater clarity in guiding digital health strategy. HIMSS is proposing the following definition of digital health, informed by a critical analysis of literature as well as digital health models and frameworks:

“Digital health connects and empowers people and populations to manage health and wellness, augmented by accessible and supportive provider teams working within flexible, integrated, interoperable, and digitally-enabled care environments that strategically leverage digital tools, technologies and services to transform care delivery.”

In order to inform health system strategy to advance digital health transformation, we also developed a measurement tool—[the HIMSS Digital Health Indicator \(DHI\)](#)—to measure and document progress toward a digital health system. DHI measures progress toward a digital health system that enables consumers to manage their health and wellness using digital tools, supported by connectivity with clinicians and provider teams, in a secure and private interoperable digital environment whenever and wherever care is needed. Operational and care delivery processes are outcomes-driven, informed by data and real-world evidence to achieve exceptional quality, safety and performance that is sustainable. DHI guides health system leaders by measuring progress towards digital health systems, as well as transformation of digital care delivery that is focused on outcomes, and informed by data as well as real-world evidence.

In addition, HIMSS and PCHalliance ask ONC to look at revising its Strategic Plan's definition of interoperability and leverage HIMSS's work on [Interoperability in the Healthcare Ecosystem and our Four Levels of Interoperability](#). We define interoperability as the following:

“the ability of different information systems, devices and applications ('systems') to access, exchange, integrate and cooperatively use data in a coordinated manner, within and across organizational, regional and national boundaries, to provide timely and seamless portability of information and optimize the health of individuals and populations globally”

Building on Foundational (Level 1), Structural (Level 2), and Semantic (Level 3), HIMSS added Organizational (Level 4) interoperability, that includes governance, policy, social, legal and organizational considerations to facilitate the secure, seamless and timely communication and use of data both within and between organizations, entities, and individuals. These components enable shared consent, trust, and integrated end-user processes and workflow.

The workforce issue is also of paramount importance as we think about how the community will effectively meet the goals and objectives outlined in this Strategic Plan. Informatics expertise must be fully integrated into the health provider workforce to adequately assess, design, implement and evaluate the effectiveness of health IT capabilities. The workforce needs support from an educational as well as advocacy perspective around hiring processes and valuing these experts in the workplace. ONC and its federal partners need to ensure that informatics professionals are leveraged to inform health IT design, workflow efficiency, data integrity, and optimization.

Overall, the Plan's strategic goals and objectives capture important themes that ONC should concentrate on over the next five years. For our public comment, we offer the following thoughts and recommendations on specific objectives and strategies, with the goal of creating an environment where the federal government collaborates with all healthcare stakeholders to empower patients while delivering better outcomes as well as higher quality and more cost-effective care:

Goal 1: Promote Health and Wellness

Objective 1a: Improve individual access to health information

HIMSS and PCHAlliance support the efforts across the Department of Health and Human Services (HHS) to provide patients with secure access to their personal health data and analytics tools that engages every individual to direct their own healthcare as well as inhibits the blocking of information that contributes to more seamless care delivery.

In addition, ONC and Centers for Medicare & Medicaid Services (CMS) Interoperability Regulations help set a course for a healthcare paradigm that takes full advantage of the promise of standards-based application programming interface (API) technology, and capitalizes on the inherent opportunities for innovation while making allowances for encouraging new market entrants. Overall, we appreciate the opportunity to help HHS create a new healthcare ecosystem through these regulations that reinforces the secure access to, exchange of, and use of electronic health information, and welcome the emphasis in the Strategic Plan.

Moreover, we encourage ONC to ensure that the federal government is focused on promoting the exchange of data that is useful for improving care processes and empowering patients. Priority should be placed on the quality, value, and usefulness of the information that is interoperable and being exchanged. Success in this endeavor is not simply moving information between providers, or from providers to patients, but moving the right information to and from all system participants when and where it is needed to inform decisions. Given broader concerns about minimizing clinician burden, we do not support potentially overloading information exchange processes without demonstrated utility of that information for clinicians as well as patients.

To encourage even more individual access to information, the federal government should work with the healthcare community to define the value proposition for all healthcare ecosystem participants related to the collection and exchange of data. Such dialogue could better promote the idea of why individuals should demand control over their health information and how health and wellness outcomes are improved as data moves effortlessly across the continuum of care.

Another critical component to interoperability is ensuring that the patient contribution is valued and incorporated into any discussions about exchange moving forward. Health IT needs interoperability between patients/consumers and providers that allows individuals to access and contribute to information that is created and retained by providers in electronic health records (EHRs) through the inclusion of Patient Generated Health Data. The next phase of ONC's federal policy development needs to capitalize on the importance of patient contributions to their EHRs. Expanding an individual's access to their data has been the policy focus over the past three years, and now we encourage a shift of that paradigm to take advantage of an individual's contributions to patient reported outcomes and connected care with providers that is meaningful to patients.

A potential model to consider is the work that CMS is doing to update the Merit-based Incentive Payment System (MIPS) Program to launch the MIPS Value Pathways (MVP) Program. In the next three to five years, MVP will incorporate the voice of the patient into its payment and incentive structure, and provide enhanced performance feedback that is meaningful to clinicians as well as patients. Working to incorporate patient-generated health data and patient-reported outcomes into an individual's record and contribute to the development of a care plan should also be considered moving forward.

Overall, we encourage ONC to continue to drive greater individual access to information, but urge the Strategic Plan to also include more emphasis on two-way information/data exchange and outcomes reporting between individuals and clinicians. Enabling dynamic, two-way exchange processes is the next critical phase of work needed on behalf of individuals.

Goal 1: Promote Health and Wellness

Objective 1c: Integrate health and human services information

HIMSS and PCHAlliance support the inclusion of this objective and how ONC and its federal partners want to better leverage Social Determinants of Health (SDOH) Data. Little integration of data exists between the various federal, state, territorial, regional and local agencies, and tribes, but more coordination is needed across governments to ensure that the community can appropriately address SDOH and other issues.

There is also a gap in the development of the infrastructure needed to support information exchange on behalf of social service providers and the actual exchange of SDOH Data. Building this infrastructure requires several steps: establishing needed exchange policies and protocols; supporting the awareness, adoption, and use of exchange across the sector as well as for patients; and, creating the needed technical backbone to perform the exchange.

Overall, capturing and using SDOH data to understand health outcomes and the conditions under which the best outcomes are achieved for patients is the next frontier for the healthcare enterprise. We agree that the initial step is building-up the IT infrastructure of the local community-based organizations that may not have resources or the expertise to exchange patient-level data with clinicians and health systems. HIMSS and PCHAlliance encourage ONC and CMS to explore how to use value-based care incentives through accountable care organizations (ACOs) or other innovative care delivery models from the Center for Medicare and Medicaid Innovation (CMMI) to spur investment in this area.

Other topics that need to be prioritized are the privacy and security of this information as the SDOH infrastructure is developed. Much of an individual's SDOH Information is considered sensitive, but is collected and managed separate from HIPAA covered entities, and assurances are needed that it will be protected as such. In addition, collecting and using SDOH Information needs to be configured in such a way that it does not add to a clinician's workload or burden issues.

Moreover, provider education on the resources that are available in their specific community is needed. Some providers have been reluctant to screen for SDOH because they are not aware of where to refer a patient in need or if the capacity is available at a particular community service provider. ONC and its partners should work to encourage states/localities to create Social Services Directories for specific geographic regions. Such resources will be extremely helpful in informing communities on the services that are available for referrals, and help ensure that this objective is achievable.

Goal 2: Enhance the Delivery and Experience of Care

Objective 2a: Ensure safe and high-quality care through the use of health IT

We appreciate the focus on better positioning healthcare providers to develop care plans and delivering high quality, safe, person-centered care through the deployment of tools that collect, store, and use health data that addresses the unique needs of each individual patient. There are several strategies that HIMSS and PCHAlliance want to highlight in support of this objective.

We support the idea of optimizing care delivery by applying advanced capabilities like machine learning and clinical decision support (CDS) software. HIMSS and PCHAlliance have been very involved the Food and Drug Administration's work on [developing a CDS software regulatory framework](#) that sustains rather than stifles innovation in order to drive healthcare transformation. To optimize care delivery, we recommend that there be an acceptable level of clarity and predictability in terms of regulation and/or oversight while continuing to support reasonably safe and effective medical devices. The nature of health IT and its role in health care delivery decisions continues to evolve, and we recommend that any new policy offer predictable regulatory processes for health IT products.

Expanding care beyond traditional clinical settings through access to remote monitoring, telehealth, and other mobile and health IT services is also an important target. HIMSS and PCHAlliance remain on the front lines of these policy discussions, focused on expanding access to reliable and affordable telehealth services and remote patient monitoring technologies. We recommend using all available policy levers offered through CMS payment policy to increase adoption.

HIMSS and PCHAlliance are also supportive of efforts to establish identity solutions that improve patient matching across data systems. We look forward to working with ONC as it develops its congressionally-mandated report to evaluate the effectiveness of current methods that improve identification of patients and makes recommendations to Congress. HIMSS has long been involved in leading private sector efforts to improve patient matching, including funding an Innovator-in-Residence at HHS who worked on this topic. It was the work of the HIMSS Innovator-in-Residence that led to the ONC [Patient Matching Algorithm Challenge](#) in 2017.

HIMSS strongly supports the use of matching algorithms as part of an overall patient matching strategy, which should include work to create a benchmark measurement for algorithms that have been and will be developed. This benchmark would help providers, organizations, and potentially CMS decide which algorithm to use moving forward.

In terms of expanding use of safer clinical practices, HIMSS and PCHAlliance recommend that ONC work with the Agency for Healthcare Research and Quality (AHRQ) to fully implement a provision of the [21st Century Cures Act](#) focused on treating developers as providers for patient safety organization (PSO) reporting purposes. PSO participation would enable methods and approaches for appropriate investigation of safety events or risks in a protected space. This step would help create a culture of safety across the health IT ecosystem.

HIMSS and PCHAlliance also support using electronic clinical quality measure (eCQM) data to optimize healthcare providers' and researchers' abilities to assess quality and outcomes. We want to ensure the reported data from eCQMs are actionable, and can be utilized to identify gaps in care, conduct workflow and root cause analysis for performance outcomes, and trigger change management to adjust workflows and best practice guidance that will drive improved outcomes. In addition, we have long supported robust field-testing of new eCQMs prior to their release by CMS, as field-testing would reduce the burdens of workarounds and modifications that are sometimes needed in eCQM implementation.

For precision medicine, HIMSS and PCHAlliance express support for the [All of Us Research Program](#) and encourage ONC to ensure that the Strategic Plan highlights opportunities to better leverage the program as our health system customizes care and targets treatment options for individual patients. As previously discussed, this is also an opportunity to highlight the importance of establishing two-way data exchange between individuals and clinicians to document and report outcomes. This step further enables the traceability of outcomes at both the personal and population segment level to determine quality and safety of care based on one's genetic information—which will be required for any personalized medicine program to succeed.

Goal 2: Enhance the Delivery and Experience of Care

Objective 2c: Reduce regulatory and administrative burden on providers

HIMSS and PCHAlliance thank ONC and its partners for including this objective in the Strategic Plan. We appreciate that healthcare is complex and often requires hard work and extraordinary effort on the part of clinicians to arrive at the right diagnoses as well as to provide appropriate treatment. Our belief is that this level of effort defines our members' clinical work as professionals. That said, much of the work that clinicians face today is unnecessarily burdensome, where burden is defined as clinician activity that does not serve patient interests, does not improve quality or safety, or regardless of intent, is a barrier to clinical workflow and limits the ability of clinicians to appropriately engage with patients.

We want to work with ONC and CMS to eliminate the unnecessary actions that occur in the course of clinical practice. We call on HHS to remain vigilant in its efforts to minimize clinician burden as well as the reporting or administrative requirements placed on clinicians that do not support the delivery of outcomes-focused, value-based care.

It is critical to ensure the data clinicians are utilizing are high-quality and work for the practitioner as well as the patient. How clinicians can visualize patient data is a key component and should be part of any solution to address burden. In addition, optimizing the use of the eCQMs, including ensuring that we are minimizing data collection burden is critical. Moreover, harmonizing federal, state, and private payer reporting requirements would be a significant step forward. As part of this strategic planning process, we encourage HHS to consider convening stakeholders from across the continuum, including states and private payers, to discuss the creation of a core data set to help streamline reporting requirements, and take appropriate action to coordinate with the transition from the United States Core Data for Interoperability (USCDI) to the new electronic protected health information (ePHI) requirements identified in the Interoperability and Information Blocking Final Regulation.

Goal 3: Build a Secure, Data-Driven Ecosystem to Accelerate Research and Innovation

Objective 3b: Support research and analysis using health IT and data at the individual and population levels

HIMSS and PCHAlliance pledge to work with ONC and its federal partners to use this Strategic Plan to support research and innovation advances. However, we want to stress that we are not focused on just increasing the uptake of new technology, but we want to target the adoption and use of new technology and ensure any technology's applicability to healthcare before proceeding.

Other elements that would support research and analysis using health IT revolve around impending changes to the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and how any changes can support research. Responsible reforms to HIPAA offer opportunities to better harness data, support research endeavors, and allow patients to direct the movement of health data. Helpful HIPAA reforms would include making consent to ethically use data for research purposes available concurrently with consent to treat and exchange data in the course of care. In addition, changes to the Common Rule that excluded low-risk health IT-related research from institutional review board review would be a huge catalyst to expand research opportunities.

Moreover, given the public health response to the COVID-19 pandemic, this Strategic Plan offers an opportunity to facilitate support for more rapid sharing of disease surveillance data. The importance of public health surveillance, the interactive system of

governmental public health agencies at the federal, state, local, tribal, and territorial levels working with health care providers and to detect, report, respond to, and prevent illness and death, has been highlighted by the ongoing pandemic. We encourage ONC to work with the Centers for Disease Control and Prevention (CDC) to take a system-wide, enterprise approach to strengthen the public health core infrastructure by expanding, enhancing, and improving public health data systems at CDC, as well as at state, local, tribal, and territorial health departments. An interoperable public health surveillance system is critical to effective and timely public health response, prevention, and policy development, and will allow the public health community to detect public health threats sooner and ultimately save lives.

Goal 4: Connect Healthcare and Health Data through an Interoperable Health IT Infrastructure

Objective 4c: Enhance technology and communications infrastructure

The United States must close the digital divide that exists in this country by making crucial investments in broadband deployment. Reliable and affordable broadband is necessary to realize the full potential of digital health technologies and improve access to high quality care for all Americans. Yet, according to the Federal Communications Commission (FCC), at least 21.3 million Americans, mostly in rural and underserved areas, [still lack access to broadband](#). Research shows this lack of access is negatively affecting both patients' health and clinicians' ability to provide the care needed [to make their communities healthier](#).

HIMSS and PCHAlliance recommend ONC use the Strategic Plan to work with its federal partners to help build the needed technology and communications infrastructure across the entire nation. FCC's Universal Service Fund (USF) provides an opportunity to redirect some federal government funds for these purposes with some thought and effort. In addition, we encourage greater alignment between FCC's Healthcare Connect Fund and the US Department of Agriculture's broadband programs on how each supports the needs of rural communities. Communities should be able to access funding that supports their entire broadband technology needs to improve the reach of healthcare services, not just funding dedicated for healthcare services.

Moreover, we need mechanisms to improve technology and infrastructure for communication with patients, particularly in rural and remote communities where access to care is a challenge. Right now, the default position is that municipalities provide last mile broadband access, although they are not necessarily incentivized to provide these services. This Strategic Plan should examine how to support municipalities in the provision of this last mile access and ensure that patients have opportunities to maintain appropriate communication levels with healthcare providers as well as for other services. Federal

agencies should not only promote building a broadband infrastructure, but a broader regulatory regime that encourages patient engagement and access to information.

In terms of scaling this infrastructure, HIMSS and PCHAlliance appreciate the inherent opportunities that deploying cloud-based services provide the storage and exchange of information. Moreover, building this infrastructure provides opportunities to adopt telehealth services to reach patients outside of traditional care settings. We want to expand access to evidence-based telehealth services to better meet the needs of Medicare beneficiaries as well as other patients. Evidence-based telehealth will improve access to high-quality care and address many accessibility issues that underserved areas and beneficiaries often face.

Goal 4: Connect Healthcare and Health Data through an Interoperable Health IT Infrastructure

Objective 4d: Promote secure health information that protects patient privacy

The privacy and security of an individual's health information are the foundational building blocks of greater interoperability and data exchange efforts, with HIPAA providing the regulatory framework to enable more data sharing. This objective is critically important as we discuss the next phase of interoperability, both within a HIPAA-regulated environment as well as outside the purview of HIPAA Regulations.

HIMSS and PCHAlliance support the current HIPAA Regulations, specifically the role of the patient as the primary authority in designating access to their data. In addition, we reaffirm that organizations should not be able to share an individual's data for purposes other than treatment, payment, or health care operations without the expressed consent of that individual.

As HIPAA evolves, we envision that it should include a more explicit patient-centered consent framework that is straightforward for providers to administer and gives the patient the ability to share their data with another healthcare institution or a specific practitioner as well as provides the patient the opportunity to segment some of their data for sharing for a particular period of time. Patients should have the means to identify care team members and data without an originating provider's knowledge or provider's affiliation with any care team. Under any scenario, the key principles are that the patient is involved, engaged, and at the center of any decision-making involving the sharing of their personal data. To promote secure health information that protects patient privacy, we are looking to Congress to address the privacy and security impact of individual access and data exchange outside of HIPAA.

Moreover, HIPAA alignment with other laws and regulations is a key consideration when thinking about potential regulatory changes. The patchwork of existing state laws focused on health information privacy make for a challenging environment when attempting to share data. Most of these state laws are not preempted by HIPAA, so inter- as well as intra-jurisdictional information sharing is impacted by myriad regulations and uncertainty over what rules apply in particular circumstances. This has the potential to lead to hyper-interpretation as a means to achieve compliance as opposed to supporting the efficient sharing of key health information to advance high quality, valued-based care. We encourage HHS to investigate how to harmonize any new iteration of HIPAA with other laws.

Finally, technology transformation is occurring at all levels of government. HIMSS and PCHAlliance recognize the technology modernization efforts occurring at the Departments of Defense and Veterans Affairs, and the US Coast Guard, will have significant impact on care delivery for those beneficiaries, and information sharing expectations across the US. We strongly encourage ONC to highlight and leverage those efforts and other modernization initiatives across the entire government as part of this Strategic Plan.

HIMSS and PCHAlliance appreciate the opportunity to provide comments on the Draft 2020-2025 Federal Health IT Strategic Plan. We remain committed to fostering a culture where health information and technology are optimally harnessed to transform health and healthcare by improving quality of care, enhancing the patient experience, containing cost, improving access to care, and optimizing the effectiveness of public payment.

We look forward to the opportunity to discuss these issues in more depth. Please feel free to contact Jeff Coughlin, HIMSS Senior Director of Government Relations, at jcoughlin@himss.org, or, Robert Havasy, Managing Director of PCHAlliance, at rhavasy@pchalliance.org, with questions or for more information.

Thank you for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Harold F. Wolf III". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Harold F. Wolf III, FHIMSS
President & CEO